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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,986	11/19/1999	DANIEL JOSEPH OMAHONY	99.1064.US	8043
7590 Marilou E. Watson Synnestvedt & Lechner LLP 2600 ARAMARK Tower 1101 Market Street Philadelphia, PA 19107-2950			EXAMINER ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1652	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/20/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/443,986	OMAHONY, DANIEL JOSEPH	
	<b>Examiner</b>	<b>Art Unit</b>	
	Hope A. Robinson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 114, 118-136 and 139-144 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 114, 118-136 and 139-144 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.
2. Applicant's response to the Office Action mailed October 23, 2006 on November 22, 2006 is acknowledged.

### ***Claim Disposition***

3. Claims 114, 118-136 and 139-144 are pending and are under examination.

### ***Withdrawn-Specification Objections***

4. Previous objection to the specification are withdrawn by virtue of submission of an amendment.

### ***New-Claim Objection***

5. Claims 114, 126 and 139-144 are objected to because of the following informalities:

For clarity and precision of claim language it is suggested that claim 114 is amended to read "A retro-inverted D-peptide comprising an amino acid sequence selected from the group

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consisting of SEQ ID NO:1 (ZElan 144), SEQ ID NO:2 (ZElan 145) and SEQ ID NO:3 (ZElan 146), wherein said peptide...". See also claim 126, which has similar claim language.

Claims 139-144 are objected to for the recitation of "A composition of claim X" instead of "The composition of claim X". For consistency and clarity, it is suggested that these claims are amended.

***Withdrawn-Claim Rejections - 35 USC 101***

6. Previous rejection to the claims under 35 U.S.C. 101 are withdrawn by virtue of submission of an amendment.

***Maintained and Amended-Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 114, 118-136 and 139-144 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 114 and the dependent claims hereto are directed to a retro-inverted peptide comprising SEQ ID NOS:1-3; said sequences are 15, 16 and 14 amino acids in length, respectively, wherein said peptide binds to a gastro-intestinal tract transport receptor (i.e. HPT1, hPEPT1, D2H, and hSI. The specification lacks adequate description with respect to where in the structure of the receptors recited in the claims the peptide will bind. For example, hPEPT1 is known in the art to have 708 amino acids in the structure. Note that the WO98/51325 document relied upon disclose that the above receptor domains were cloned and expressed as His-tag fusion proteins, with the following amino acids in their domains "391-571 (hPEPT1); 29-273 (HPT1); 272-667 (hSI) and 387-685 (D2H). This appears to be the binding portion of the receptors, however, the instant specification lacks guidance with regard to this aspect of the claimed invention. In addition, claims 121, 126 and the dependent claims hereto (122-125, 129-131, 136, 141 and 144) are directed to a composition comprising a retro-inverted peptide comprising an active agent; and a composition comprising a chimeric protein, respectively. The claims do not set forth what the active agent is intended to be, thus reads on a genus of agents. It is noted that claim 122 establishes that the active agent is a drug, however, a broad genus is still encompassed with this recitation. Further, it is noted that claim 139 for example recites a laundry list of active agents, however, claims 121 and 126 are not limited to said list. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas

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that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

8. Claims 114, 118-136 and 139-144 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabled for the full scope of the claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary, Amount of direction or guidance presented, Presence or absence of working examples, Nature of the Invention, Predictability or unpredictability of the art and Breadth of the claims. The relevant factors are discussed below.

Claims 114 and the dependent claims hereto are directed to a retro-inverted peptide comprising SEQ ID NOS:1-3; said sequences are 15, 16 and 14 amino acids in length, respectively, wherein said peptide binds to a gastro-intestinal tract transport receptor (i.e. HPT1, hPEPT1, D2H, and hSI. The specification lacks adequate description with respect to where in the structure of the receptors recited in the claims the peptide will bind. For example, hPEPT1 is known in the art to have 708 amino acids in the structure. Note that the WO98/51325 document

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relied upon disclose that the above receptor domains were cloned and expressed as His-tag fusion proteins, with the following amino acids in their domains "391-571 (hPEPT1); 29-273 (HPT1); 272-667 (hS1) and 387-685 (D2H). This appears to be the binding portion of the receptors, however, the instant specification lacks guidance with regard to this aspect of the claimed invention. In addition, claims 121, 126 and the dependent claims hereto (122-125, 129-131, 136, 141 and 144) are directed to a composition comprising a retro-inverted peptide comprising an active agent; and a composition comprising a chimeric protein, respectively. The claims do not set forth what the active agent is intended to be, thus reads on a genus of agents. It is noted that claim 122 establishes that the active agent is a drug, however, a broad genus is still encompassed with this recitation. Further, it is noted that claim 139 for example recites a laundry list of active agents, however, claims 121 and 126 are not limited to said list. The specification does not provide adequate guidance to be able to practice the claimed invention commensurate in scope with the claims. To examine every drug to determine if said composition will produce the effect desired would require undue experimentation. In addition, there is no indicia as to the binding specificity to the receptors.

The working example provided discusses an animal study involving the bioavailability of insulin (see for example page 26, Table 5 of the specification), however, this example does not provide support for the unspecified amount of active agents encompassed by the claims. Therefore, it is difficult to ascertain the nature of the claimed invention from this one record.

The nature of the invention is a retro-inverted peptide that specifically binds to gastrointestinal tract receptor. However, the specification does not provide sufficient guidance/direction to enable the full scope of the claimed invention.

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It is disclosed in the specification on page 3 that the applicants have found retro-inverted forms of the GIT targeting agents specific receptor sites *in vivo* and/or promote uptake of active agents and/or enhance active agent delivery across the GIT into the systemic circulation. However, the claims are directed to any possible "active agents".

Since very little is known in the prior art about the nature of the invention, renders the art unpredictable. Thus, the specification should then give more details as to how to make and use the invention in order to be enabling.

The breadth of the claims are very broad and encompass any active agent/drug in association with the claimed invention. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 121-126, 129-131, 133, 135-136 and 139-144 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 121 is indefinite for the recitation of "composition bound to a material comprising an active agent wherein said active agent treats a mammalian disorder/disease" because the active agent that is undefined which appears to be the crucial ingredient in the medicament. See also claim 126. The dependent claims hereto are also included.

Claims 133, 135, 139, 142 and the dependent claims hereto are indefinite because the claims represent improper Markush claims. A proper Markush grouping is A, B, C and D.

***Withdrawn-Claim Rejections - 35 USC § 102***

10. Previous rejection to claims under 35 U.S.C. 102 is withdrawn by virtue of submission of an amendment and arguments.

***Response to Arguments***

11. Applicant's remarks have been considered. Note that rejections remain under 35 U.S.C. 112, first and second paragraphs for the reasons stated above. These rejections have been

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amended as the issues of record have been obviated with the amendments submitted. In addition, new objections have been raised over the instant claims for the reasons stated above.

***Conclusion***

12. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Primary Examiner

HOPE ROBINSON  
PRIMARY EXAMINER